OCT 2 6 2012

K122325

7. 510(K) SUMMARY PER 807.92(A)(1)

Date Prepared: July 27, 2012

Submitter's Information

Owner/Operator:

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Submission Contact Information

Name:	Jack Slovick
Title:	Quality and Regulatory
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Proposed Device

Classification name:	Dressing, Wound, Collagen
Class:	Unclassified
Product Code:	KGN

7.1 Indications for Use

The management of burns, sores, blisters, scrapes, ulcers, and other wounds.

7.2 Description of Device

SkinTemp II Dressing is a sterile, disposable, single use wound dressing. It is a hydrocolloid and hydrophillic dressing composed of fibrous type I bovine collagen. The device is to be provided in hydrated as well as dry form. The device is to be used for the management of burns, blisters, sores, scrapes, ulcers and other wounds. The SkinTemp II Dressing will be available in 2"X2", 3"X4" and 8"X12" sizes and additional sizes may introduced at a later time.

Product List

SkinTemp dressings are available in the following sizes:

- 2" x 2" Sterile dressing (ST 1022)
- 3" x 4" Sterile dressing (ST 1002)
- 8" x 12" Sterile dressing (ST 1003)

ST 1022

- Sterile Product
- Packaged for a shelf life of 5 years in US conditions
- Moisture Content: < 17%
- Size: 2" ± 0.25" x 2" ± 0.25 "
- Heavy Metals: < 10 ppm

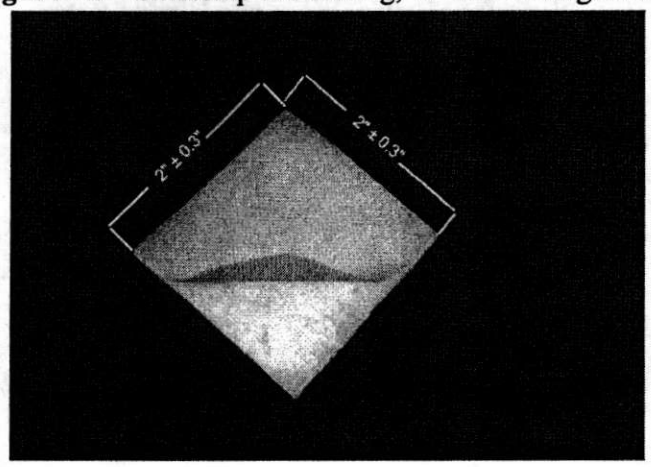
ST 1002

- Sterile Product
- Packaged for a shelf life of 5 years in US conditions
- Moisture Content: < 17%
- Size: 3" ± 0.25" x 4" ± 0.25 "
- Heavy Metals: < 10 ppm

ST1003

- Sterile Product
- Packaged for a shelf life of 5 years in US conditions
- Moisture Content: < 17%
- Size: 8" ± 0.25" x 12" ± 0.25 "
- Heavy Metals: < 10 ppm

Figure 7.1 - Skintemp II Dressing, 2" x 2" configuration



7.3 Product Materials

- Collagen
- Distilled water
- Buffering agent (HBS proprietary name 'Chemical Z')

7.4 Predicate Device

Biocore Inc. SkinTemp sheet (K913023 & K925545)

7.5 Summary of Technical Characteristics

SkinTemp II Dressing is packaged as a low moisture hydrocolloid collagen wound dressing which gives SkinTemp II Dressing the advantage of being able to absorb liquid exudates and the flexibility to conform to most wound sites. Collagen protects the wound bed and newly formed granulation tissue by formation of a protective covering that is conducive to wound healing.

The HBS SkinTemp II Dressing is comparable in design and function to the predicate device: Biocore Inc. Skintemp sheet. Per 21 CFR Part 807.92(a)(5), the following table shows where the Human Biosciences, Inc. SkinTemp II Dressing is similar to and different from the Biocore SkinTemp sheet in terms of technological characteristics:

Table 7.1: Human Biosciences, Inc. SkinTemp II Dressing and Biocore Inc. SkinTemp Sheet (predicate device) Comparison:

Feature/ Characteristic	HBS SkinTemp II Dressing	Biocore Skintemp Sheet	Comparison
510(k) #	TBD	K913023 & K925545	N/A
Intended Use/ Indications	The HBS SkinTemp II Dressing is indicated for the management of burns, sores, blisters, scrapes, ulcers, and other wounds.	The BioCore SkinTemp sheet is indicated for the management of burns, sores, blisters, scrapes, ulcers, and other wounds.	Identical

Feature/ Characteristic	HBS SkinTemp II Dressing	Biocore Skintemp Sheet	Comparison
Principles of Use	Brief Instructions for Use: Cleanse the wound. Apply medication if needed. Apply dressing and cover with non-adherent dressing. Change as required.	Brief Instructions for Use: Cleanse the wound. Apply medication if needed. Apply dressing and cover with non-adherent dressing. Change as required.	Identical
Scientific Technology	The SkinTemp II Dressing uses 100% type I bovine collagen as its primary constituent.	The SkinTemp Sheet uses 100% type I bovine collagen as its primary constituent.	Identical
Configuration / System Components	Sterile, disposable, single use, collagen based wound dressing with non adherent backing. Further properties include: a) Hydrocolloid b) Absorbent Dressing c) Gel formation	Sterile, disposable, single use, collagen based wound dressing with non adherent backing. Further properties include: a) Hydrocolloid b) Absorbent Dressing c) Gel formation	Identical
Shipping configuration	SkinTemp II Dressing is packed in primary packaging in the form of a Tyvek pouch (1059B) and is then packed in secondary packing for additional protection	SkinTemp Sheet is packed in primary packaging in the form of a Tyvek pouch (1059B) and is then packed in secondary packing for additional protection	Identical
Reusable or Single Patient Use	Single Patient use	Single patient use	Identical
Biocompatible	Yes	Yes	Identical

Feature/ Characteristic	HBS SkinTemp II Dressing	Biocore Skintemp Sheet	Comparison
Sterility	Each dressing is sterilized using Electron Beam Sterilization	Each sheet is sterilized using Electron Beam Sterilization	
Materials	Type I Bovine Collagen Distilled Water Buffering agent / Chemical Z (proprietary name)	Type I Collagen Distilled Water Buffering Agent / Chemical Z (proprietary name)	Identical
Size	SkinTemp II Dressings are to be available in 2"x2", 3"x4"& 8"x12" sizes	SkinTemp sheets are available in 2"x3", 3"x4" & 8"x12" sizes	Similar barring one configuration.

7.6 Summary of Non-Clinical Testing/Statement of Equivalence

The Human Biosciences, Inc. device is analogous to the predicate device (BioCore Skintemp sheet). Both are considered surface devices that come in contact with breached or compromised surfaces. They both have identical indications and instructions for use. Both have identical technological characteristics and have the same general shape, size and principles of use. Both devices consist of bovine collagen as the principle component. Finally, both have identical patient contact per ISO10993-1.

Multiple tests concerning product functionality, biocompatibility, packaging and sterilization have been performed on the SkinTemp device to ensure that it is as safe and as effective as the predicate device. Testing was performed to verify that the performance characteristics of SkinTemp II Dressing are analogous to the predicate device. Testing includes:

a) **Biocompatibility:** Testing has confirmed that SkinTemp II Dressing meets all biocompatibility testing requirements stated by FDA regulations and ISO 10993. Biocompatibility tests were performed by North American Science Association, Inc. (NAmSA) in accordance with proper regulations. Biocompatibility testing has shown that this device is safe for use as a medical device for wound management. The results of the testing are detailed in Section 17 and full NAmSa studies are attached in Appendix B.
b) **Sterilization:** SkinTemp II Dressings are to be eBEAM Irradiation sterilized per the recommendations of AAMI TIR-27 document titled: Sterilization of healthcare products - Radiation Sterilization Substantiation of 25kGy as a Sterilization Dose Method VD Max. The product has been validated and routine control of the sterilization process has been

created in accordance with the recommendations set forth in ISO 11137-1:2006; Sterilization of medical devices- Validation and routine control of sterilization by irradiation. The complete details about sterilization validation and dose audits are detailed in Section 16.

c) **Design Verification:** Design verification testing via functional testing of SkinTemp II Dressing is detailed in Section 20.2. This testing included General Physical Requirements, Dimensional Analysis, Visual Inspections, Moisture Content testing, Package and Labeling requirements and Operational Environment Requirements.

d) **Process Validation:** SkinTemp II dressings are to be manufactured in an ISO 13485:2003 certified cleanroom environment. The environment certifications are conducted annually and are available on plant site. Furthermore, complete process validation testing has also been performed and is detailed in Section 20.3.

7.7 Conclusion

SkinTemp II Dressing is equivalent in design, function, materials and intended use and is therefore substantially equivalent to the predicate device: BioCore SkinTemp sheet. Although both devices identical in all respects, HBS has been directed by the FDA through a warning letter dated May 10, 2012 to specifically document the use of the proprietary buffering agent 'Chemical Z' in a new 510k for SkinTemp. Biocore Inc. did not include this agent in its SkinTemp sheet 510k approvals (K913023 & K925545; filed in 1991 & 1993 respectively) due to confidentiality reasons. However, BioCore maintained full disclosure of the use of this agent from the beginning, both in its internal documents and with the FDA. FDA inspectors were made aware of the use of this buffering agent as back as 1994 during routine inspections. However, this 'Chemical Z' was never formally documented in a 510k approval. This buffering agent acts a preservative that protects the collagen in the device and helps extend the shelf life of the product prior to use. The agent is completely inert and has no active properties whatsoever. It is HBS' intention to file a new 510k for SkinTemp II Dressing and thereby formally document an ingredient that has always been part of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2012

Human Biosciences, Incorporated
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Mr. Jack Slovick
President, Quality and Regulatory Affairs
2913 209th Lane Northwest
Oak Grove, Minnesota 55011

Re: K122325
Trade/Device Name: Skin Temp II Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 10, 2012
Received: October 15, 2012

Dear Mr. Slovick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

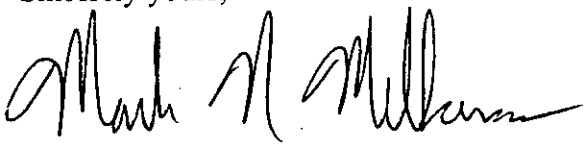
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Human BioSciences

6. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Pending K122325

Device Name: SkinTemp II Dressing

Indications for Use: The device is intended for the management of burns, sores, blisters, scrapes, ulcers, and other wounds.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices